Initial Approval Date: July 10, 2019
Revised Dates: July 8, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Plaque Psoriasis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™, Abrilada™)
Apremilast (Otezla®)
Brodalumab (Siliq™)
Certolizumab (Cimzia®)
Etanercept (Enbrel®, Erelzi™, Eticovo®)
Guselkumab (Tremfya®)
Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™, Avsola™)
Ixekizumab (Taltz™)
Risankizumab (Skyrizi®)
Secukinumab (Cosentyx™)
Tildrakizumab (Ilumya™)
Ustekinumab (Stelara™)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a dermatologist.[1,2]
- Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to methotrexate.[3] If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[3,8,14,15,16,17]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of ONE of the following criteria:
    - Moderate to Severe Plaque Psoriasis defined as one of the following: [1]
        - Body surface area (BSA) involvement > 3%.
        - Location on hands, feet, scalp, face, or genital area.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Plaque Psoriasis Agents (PsO)[4-22,25]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-12 and -23 Inhibitors			
Ustekinumab (Stelara™)	PsO	≥ 12 years	≤ 100 kg: 45 mg initially SC at weeks 0 and 4, followed by 45 mg every 12 weeks thereafter. > 100 kg: 45-90 mg initially SC at weeks 0 and 4, followed by 45-90 mg every 12 weeks thereafter.

Interleukin-17a Inhibitors			
Secukinumab (Cosentyx™)	PsO	≥ 18 years	150-300 mg SC once weekly at weeks 0, 1, 2, 3, and 4, followed by 150-300 mg every 4 weeks.
Ixekizumab (Taltz™)	PsO	≥ ~~18~~6 years	Adults: 160 mg initially SC, followed by 80 mg at weeks 2, 4, 6, 8, 10 and 12, followed by 80 mg every 4 weeks. Pediatrics weighing >50 kg: 160 mg initially SC, followed by 80 mg every 4 weeks. Pediatrics weighing 25 kg to 50 kg: 80 mg initially SC, followed by 40 mg every 4 weeks. Pediatrics weighing <25 kg: : 40 mg initially SC, followed by 20 mg every 4 weeks.
Brodalumab (Siliq™)	PsO	≥ 18 years	210 mg SC at 0, 1, and 2 weeks, followed by every 2 weeks.
Interleukin-23 Inhibitors			
Guselkumab (Tremfya®)	PsO	≥ 18 years	100 mg SC at 0 and 4 weeks, followed by every 8 weeks.
Risankizumab-rzaa (Skyrizi™)	PsO	≥ 18 years	150 mg SC (given as two consecutive injections of 75 mg each) weeks 0 and 4 followed by 150 mg every 12 weeks.
Tildrakizumab-asmn (Ilumya™)	PsO	≥ 18 years	100 mg SC at 0 and 4 weeks, followed by every 12 weeks.
Phosphodiesterase-4 Enzyme Inhibitor			
Apremilast (Otezla®)	PsO	≥ 18 years	30 mg orally twice daily.
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™, Abrilada™)	PsO	≥ 18 years	80 mg initially SC on day 1, followed by 40 mg every other week beginning 1 week later (day 8).
Certolizumab (Cimzia®)	PsO	≥ 18 years	400 mg ~~initially~~ SC ~~at weeks 0, 2, and 4 followed by 400 mg~~ every other week.
Etanercept (Enbrel®)	PsO	≥ 4 years	Pediatrics: < 63 kg: 0.8 mg/kg SC once weekly, up to a maximum of 50 mg per dose. ≥ 63 kg: 50 mg SC once weekly. Adults: 25-50 mg SC twice weekly for 3 months followed by 50 mg once weekly.
Etanercept-szzs (Erelzi™~~, Eticovo®~~)* Etanercept- ykro (Eticovo®)*	PsO	≥ ~~18~~4 years	Adults: ~~25-~~50 mg SC twice weekly for 3 months followed by 50 mg once weekly. Pediatrics: ≥ 63 kg: 50 mg SC once weekly.
Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™, Avsola™)	PsO	≥ 18 years	5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous

* There is no dosage form for Eticovo or Erelzi that allows weight base dosing for pediatric patients below 63 kg (138 pounds). To achieve pediatric doses other than 50 mg, use other reconstituted etanercept products lyophilized powder.

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

DRAFT PA Criteria

- Prescriber must provide at least ONE of the following response measure(s):
  - BSA improvement ≥ 75% compared to baseline.[2]
  - BSA involvement ≤ 3%.[2]
  - Resolved involvement on hands, feet, scalp, face, and/or genital area AND no new involvement in any of these areas.
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of PsO.[3]

Conventional Psoriasis Therapy	
Generic Name	**Brand Name**
Acitretin	Soriatane®
Cyclosporine	Gengraf®, Neoral®
Methotrexate	Trexall®, Rheumatrex®, Otrexup®, Rasuvo®

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Abrilada™ (adalimumab-afzb)	Hadlima™ (adalimumab-bwwd)	Rituxan® (rituximab)
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan Hycela™ (rituximab/hyaluronidase)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Ruxience™ (rituximab-pvvr)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Siliq® (brodalumab)
Avsola™ (infliximab-axxq)	Ilumya™ (tildrakizumab-asmn)	Simponi® (golimumab)
Cimzia® (certolizumab)	Inflectra® (infliximab-dyyb)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Ixifi™ (infliximab-qbtx)	Skyrizi™ (Risankizumab-rzaa)
Cosentyx® (secukinumab)	Kevzara® (sarilumab)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kineret® (anakinra)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Nucala® (mepolizumab)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Olumiant® (baricitinib)	Truxima® (rituximab-abbs)
Entyvio® (vedolizumab)	Orencia® (abatacept)	Tysabri® (natalizumab)
Erelzi™ (etanercept-szzs)	Remicade® (infliximab)	Xeljanz® (tofacitinib)
Eticovo® (etanercept-ykro)	Renflexis® (infliximab-abda)	Xeljanz XR® (tofacitinib)
Fasenra™ (benralizumab)	Rinvoq™ (upadacitinib)	Xolair® (omalizumab)

References:

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2. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol 2017;76:290-8. Available at https://www.jaad.org/article/S0190-9622(16)30909-4/abstract. Accessed on 6/20/19.
3. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011;65:137-74. Available at https://www.jaad.org/article/S0190-9622(10)02173-0/abstract. Accessed on 6/20/19.
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5. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
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7. Otezla (apremilast) [prescribing information]. Summit, NJ: Celgene Corporation; June 2017April 2020.
8. Siliq (brodalumab) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.
9. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April September 2019.
10. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corp; May 2018March 2020.
11. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; January 2018June 2020.
12. Eticovo (etanercept) [prescribing information]. Denmark: Samsung Bioepis; April 2019.
13. Tremfya (guselkumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; April November 2019.
14. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; June 2018May 2020.
15. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; September 2018July 2019.
16. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; March 2019January 2020.
17. Ixifi (infliximab-qbtx) [prescribing information]. Ringaskiddy, Co. Cork, Ireland: Pfizer Ireland Pharmaceuticals; December 2017January 2020.
18. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2018May 2020.
19. Skyrizi (risankizumab) [prescribing information]. North Chicago, IL: AbbVie Inc; April 2019March 2020.
20. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2018January 2020.
21. Ilumya (tildrakizumab-asmn) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; August 2018October 2019.
22. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; June 2018March 2020.
23. Avsola (infliximab-axxq) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2019.
24. Hadlima (adalimumab-bwwd) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; July 2019.
22.25. Abrilada (adalimumab-afzb) [prescribing information]. New York, NY: Pfizer; November 2019.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE DATE